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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/879,719	06/12/2001	Wayne R. Curtis	PSU1886 (Div.)	6448

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EXAMINER

WARE, DEBORAH K

ART UNIT	PAPER NUMBER
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1651

DATE MAILED: 08/27/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/879,719

Applicant(s)

Curtis

Examiner

Deborah Ware

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on Jun 25, 2002
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-27 is/are pending in the application.
- 4a) Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-27 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claims \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some\* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). 4 6) ☐ Other: \_\_\_\_\_

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Claims 1-27 are presented for reconsideration on the merits.

The amendment filed May 31, 2002, has been received and entered. Further the extension of time for 2 months has been granted and appropriate fees charged. Also the Information Disclosure Statement (IDS) filed June 25, 2002, has been received and the references submitted therewith have been considered and the appropriate fee has been charged in accordance with 37 CFR 1.97(c).

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

This application is a divisional of case Serial No. 09/388,239, filed on September 1, 1999, which is now U.S. Patent No. 6,245,555. Further, the application also claims benefits to provisional applications 60/098,701, filed September 1, 1998 and 60/125,656, filed March 22, 1999. It is noted that at page 1, line 1 of the instantly filed specification Applicant has provided this information, with the exception of the status of the divisional case. Applicant is hereby requested to update the status of the divisional case at page 1, line 1 of the specification.

Further, Applicant is requested to inform the examiner as to the status of the drawings with respect to whether such drawings filed in the case are formal or informal drawings. Thus, upon such response the examiner will have the drawings reviewed by the Draftsperson once status has been indicated as formal drawings are filed. Such information would be appreciated by the examiner because it is unclear to the examiner whether the drawings are formal. Note that

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the Draftsperson will only review drawings which have been indicated by the Applicant as formal drawings.

1. Claims 1-27 remain rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

2. Applicant's arguments filed May 31, 2002, have been fully considered but they are not persuasive. Applicants have over come some of the rejections but have not over come the following rejections set forth in the last office action. It appears from Applicant's argument(s) that Applicants considered that the amendments provided in the instantly filed response of May 31, 2002, overcome all of the rejections under 35 USC 112, second paragraph, however, this is not the case and the rejection is maintained.

The step of "varying at least one of the flow rate of the aerating fluid and the composition of the aerating fluid in response to the detected characteristic" recited in the claims remains very uncertain with respect to what type of characteristic is being detected? Also "a flow rate" does not adequately describe how the cell suspension changes in response thereto, in order to possess identifying characteristics of which have not been adequately described in the claims. Thus, the metes and bounds of the claims can not be determined. Also "the composition of the aerating fluid" lacks antecedent basis in the claims.

Also claim 13 remains unclear with respect to " the step of detecting a characteristic". What characteristic is being detected? Again these phrases and terms are indefinite for these

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claims as well as claims 1-9, for the reasons as noted above. Is the characteristic some type of one which can be observed with the naked eye? Is claim 14 referring to "optically detecting" in terms of what can be observed with the naked eye, or is some type of instrument used? Also claims 13 and 15, as well as 14 and 16 appear to be essential duplicates of each other unless "varying the aerating fluid composition" is carried out differently than that of "varying the aerating fluid flow rate". It would appear that varying the aerating flow rate is how the composition is varied? Again the metes and bounds of the claims can not be determined. Also it is suggested to change "culture medium" used in claim 10 to --culture media--. Consistent use of terminology is requested as previously set forth in the last action.

Note Applicants have not addressed how can the circulating step be carried out when "the first opening" is closed after the step of "closing the first opening"? The metes and bounds of the claims are uncertain. There appears to be steps missing from the claimed method in which to clarify how the method is being carried out. Furthermore, it is unclear what the composition of the aerating fluid is? The metes and bounds are unclear. Also the characteristic of the cell culture is unclear. The characteristics have not been well defined in any of the claimed methods.

3. Claims 1-27 remain rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Smith et al. (A), hereinafter Smith.

4. Applicant's arguments filed May 31, 2002, have been fully considered but they are not persuasive. The argument that the pump disclosed by Smith is used to fill the containers prior to culturing the cells rather than controlling the flow of fluid while the cells are being cultured is

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noted. However, none of the claims 1, 10 and 17 or dependent claims therefrom require a step of "controlling the flow of fluid while the cells are being cultured" step per se. Furthermore, Smith does clearly teach that it is possible to grow suspension cells in flexible plastic containers, note column 1, lines 25-35. In addition, none of the methods require any kind of "feedback from a detected characteristic", the methods only require a "detecting" step which may be carried out by an operator or provided by input data, note column 5, lines 35-40. Detectable characteristics of a suspension culture are inherent to the teachings of Smith. Characteristics of the suspensions culture must be detectable in order for data and parameters to be useful for the suspension culturing process disclosed by Smith. At the very least the step is an obvious modification of Smith and within the purview of one of skill in the art. Note that the rejection noted above is made under 35 USC 102/103.

5. Contrary to Applicant's alleged contrast statement regarding Smith in that the previous action provided no support for a step of aerating, it should be noted that the prior action clearly stated that the pump provides flow rate as well as the step of circulating disclosed by Smith clearly teaches a flow rate since in order to circulate a fluid culture media a flow rate is required. Likewise the step of aerating a cell suspension is inherent to the circulating step disclosed by Smith since a step of aerating can be carried out by aerating. The claims do not necessarily omit the use of a pump which can also provide a step for aerating during the pumping of the culture media from one container to the next. Each of the process steps are inherent to the process carried out by Smith. Smith clearly teaches that one particular application for their pump or

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solution transfer method is for the culturing of cells, note column 6, lines 34-35 and lines 45-50.

Therefore, the argument that the pumping is carried out in the absence of cell culturing is not persuasive as Smith does teach pumping is carried out during cell culturing.

6. With respect to particular details as may be disclosed by Smith and presented as arguments by Applicants as being a different process, it is clear that each of the process steps are at least suggested if not inherent to the teachings of Smith. The methods claimed by Applicants are drafted very broadly and can read on a number of different methods, including the method and process steps disclosed by Smith. Further, in response to Applicants' argument regarding their methodology the teachings of Smith clearly teach a flow rate because in order to circulate a fluid culture media a flow rate is required. Circulating fluids (i.e. culture media) possess a flow rate.

7. In response to Applicants' argument that Smith uses preformed sealed containers that have an access port and thus, do not teach or suggest the step of attaching a liner to a closure to close an opening in the liner as recited in claim 10, it should be noted that Smith does teach a flexible container which has a layer (i.e. liner), note column 5, line 29 and roll clamps (i.e. closure) note column 5, line 65-66. The roll clamps allow for opening and closing which do indeed teach the step of providing a plastic reservoir having an opening and closing. Therefore, each of the different method claims are taught by the cited reference. In the alternative each of the methods are suggested by the cited reference. The following is the previous rejection made in the first office action:

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Claims are drawn to methods of culturing cells or microorganisms comprising providing flexible containers, introducing culture media therein, inoculating the culture media to provide a cell suspension and aerating with a fluid having a flow rate and detecting a characteristic of the suspension and varying the flow rate in response to this characteristic. Further, a circulating step is also claimed.

Smith teaches flexible containers and culturing cells or microorganisms therein. The containers are disclosed to include culture media, and furthermore, a circulating step is disclosed. Note the abstract, and columns 1, 2, 6 and 7, all lines.

The claims are identical to the disclosure of Smith and are, therefore, considered to be anticipated by the teachings of the cited reference. However, in the alternative that there is some unidentified claimed characteristic for which provides for some difference then such difference is considered to be so slight as to render the claims obvious over the cited reference. The step of varying flow rate as well as identifying a characteristic of the culture are inherent to the teachings of Smith. Clearly the pump taught by Smith provides a flow rate as well as the step of circulating disclosed by Smith clearly teaches a flow rate because in order to circulate a fluid culture media a flow rate is required. Therefore, these process steps are inherent to the culturing disclosed by Smith.

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).



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A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

All claims fail to be patentably distinguishable over the state of the art discussed above. Therefore, the claims are properly rejected.

The remaining references listed on the enclosed PTO-892 and/or PTO-1449 are cited to further show the state of the art.

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Deborah K. Ware whose telephone number is (703) 308-4245. The examiner can normally be reached on Mondays to Fridays from 9:30AM to 6:00PM.


If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mike Wityshyn, can be reached on (703) 308-4743. The fax phone number for the organization where this application or proceeding is assigned is (703) 305-3592.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

  
Deborah K. Ware

August 24, 2002



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